

K091228

SEP 28 2009

510(k) Summary

ArthroCare Corporation
ArthroCare® SpineWand®

General Information

Submitter Name/Address: ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, CA 94085-2936

Establishment Registration Number: 2951580

Contact Person: Valerie Defiesta-Ng
Director, Regulatory Affairs

Date Prepared: April 22, 2009

Device Description

Trade Name: ArthroCare® SpineWand®

Generic/Common Name: Electrosurgical Device and Accessories

Classification Name: Electrosurgical Cutting and Coagulation
Device and Accessories (21 CFR
878.4400)

Predicate Devices

ArthroCare SpineWand	K072089 (August 17, 2007)
ArthroCare System 2000	K011634 (June 19, 2001)
ArthroCare System 2000	K001588 (August 17, 2000)

Product Description

The Wands are bipolar, single use, high frequency electrosurgical devices.

Intended Use

The Wands are intended for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurological procedures.

Substantial Equivalence

This Special 510(k) proposes modifications to the dimensional specifications, materials and package of the ArthroCare SpineWands. The indications for use, technology, sterilization, principle of operation, and performance specifications of the Wands remain the same as in the predicate cleared 510(k).

Summary of Safety and Effectiveness

The proposed modifications to the Wands are not substantial changes, and do not significantly affect the safety or efficacy of the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 28 2009

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

ArthroCare Corporation
% Ms. Valerie Defiesta-Ng
680 Vaqueros Avenue
Sunnyvale, California 94085-3523

Re: K091228

Trade/Device Name: ArthroCare® SpineWand®

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: II

Product Code: GEI

Dated: September 18, 2009

Received: September 23, 2009

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K _____

Device Name: ArthroCare® SpineWand®


Indications for use:

The Wands are intended for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurological procedures.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 FOR M. MELKERSON
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091228